SENTINEL
DIAGNOSTICS

K051114

NOV 25 2005

510k Summary
Sentinel Ammonia Ultra Diagnostic Assay

K Number: _____

1. **Submitter's information:**

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3. **Date summary prepared:** 16 November 2005

4. **Device name and classification**

The Sentinel Ammonia Ultra Diagnostic Assay described in this 510(k) consists of reagent and controls, packaged and distributed in two kits, but together making up the Ammonia assay. The device is intended to be sold as an in-vitro test for professional use.

Product name and classification information are provided in Table 4.1 below.

Table 4.1 Device names and classification of Sentinel Ammonia Ultra Diagnostic Assay components

Trade/Device Name	Regulation name	Classification panel	Regulatory class	Product Code
Ammonia Ultra	Enzymatic Method, Ammonia	Clinical Chemistry	I	JIF
Ammonia Control	Single (Specified) Analyte Controls (Assayed and Unassayed)	Clinical Chemistry	I	JJX

5. Device description

The Sentinel Ammonia Ultra Diagnostic Assay described in this 510(k) submission is composed by reagent, calibrator and controls, packaged and distributed in different kits. The device is intended to be sold as an in-vitro test for professional use.

The Ammonia Ultra is an enzymatic in vitro diagnostic assay for the quantitative determination of ammonia in human plasma. Ammonia, in the presence of glutamate dehydrogenase (GLDH), combines with α-ketoglutarate and NADH to yield glutamate and NAD^+. The decrease in absorbance due to the NADH oxidation, at 340 nm, is proportional to the ammonia concentration in the examined plasma. The reagent contains lactate dehydrogenase (LDH) in excess, to rapidly reduce endogenous pyruvate so that it does not interfere with the assay system. The actual concentration of ammonia is determined multiplying the rate of absorbace per the calibration factor obtained during the calibration with the ammonia standard of 500 μg/dL included in the kit.
To ensure a correct determination during quantification of ammonia samples, a quality control procedure is required. The Ammonia Controls are liquid controls at 3 levels, prepared in bovine albumin matrix, and are used to verify the performance of the Ammonia Ultra assay. The value and range assigned to each level is specific for each lot and has been determined in rigorously standardized condition by the calculation of the median obtained in multiple determinations using reagents and standard relative to the Ammonia Ultra.

6. Intended Use

The Ammonia Ultra is intended for the in vitro quantitative determination of Ammonia (NH3) in human plasma on automated system.
Ammonia measurements are used in the diagnosis and treatment of severe liver disorders such as cirrhosis, hepatitis and Reye's syndrome" CFR 862.1065

The Ammonia Controls are intended as a means of monitoring Sentinel Ammonia Ultra assay method.

7. Comparison with Predicate Devices

Table 7.1 below provides a list of predicate devices for the Sentinel Ammonia Ultra Diagnostic Assay devices.

Table 7.1 Predicate devices for Sentinel Ammonia Ultra Diagnostic Assay devices

#	Sentinel Trade Device Name	Predicate Device Name	Predicate Device Manufacturer	Predicate device (k)	FDA clear-ance date
1	Ammonia Ultra	Ammonia-Incorporating Dynamic Stabilization Technology	Trace America, Inc	K974620	02 Jan. 1998
2	Ammonia Controls	Quantimetrix Ammonia Controls	Quantimetrix Corp.	K913346	25 Sep. 1991

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The Sentinel's Ammonia reagent and controls and the predicate devices are both used for the determination of ammonia. In addition, they use the same:

- Sample type: plasma
- Technology: enzymatic
- Detection method: NADH oxidation
- Calibration: against aqueous standard

However, Ammonia Ultra will be used with the Abbott ARCHITECT® *c*8000® analyzer, whereas the Trace Ammonia labeling indicates that the product can be used with any automated clinical chemistry analyzer.

8. Performance Data

Performance evaluations included sensitivity, intra- and inter-assay imprecision, and method comparison.

9. Conclusion

The performance and safety data presented in this premarket notification support a finding of substantial equivalence between the Sentinel Ammonia Ultra Diagnostic Assay and the predicate devices specified in this submission.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 25 2005

Mr. Davide Spada
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20155 Milan, Italy

Re: k051114
Trade/Device Name: Sentinel Ammonia Ultra
Regulation Number: 21 CFR 862.1065
Regulation Name: Ammonia test system
Regulatory Class: Class I
Product Code: JIF, JJX
Dated: September 26, 2005
Received: November 8, 2005

Dear Mr. Spada:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051114

Device Name: Sentinel Ammonia Ultra

Indications For Use:

The Ammonia Ultra is intended for the in vitro quantitative determination of Ammonia (NH3) in human plasma.

Ammonia measurements are used in the diagnosis and treatment of severe liver disorders such as cirrhosis, hepatitis and Reye's syndrome

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051114

510(k) Number (if known): K051114

Device Name: Sentinel Ammonia Controls

Indications For Use:

The Ammonia Controls are intended as a means of monitoring Sentinel Ammonia Ultra assay method.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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